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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,265

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Esben Strobec

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EXAMINER

REDDY, SATHAVARAM I

ART UNIT

PAPER NUMBER

1785

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/587,265	Applicant(s) STROBECH ET AL.	
	Examiner SATHAVARAM I. REDDY	Art Unit 1785	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 14-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/18/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-13, drawn to a product.

Group II, claim(s) 14-21, 29 and 30, drawn to a process.

Group III, claim(s) 22-28, drawn to a product.

2. The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Claims 1-30 lack unity of invention because they lack the same special technical features. For example, the product of Group I requires hydrocolloids in an elastomeric matrix and grottos which are not required by the process of Group II whereas the process of Group II requires heat treatment of an adhesive which is not required by the product of Group I. The process of Group II requires a heat source which is not required by the product of Group III whereas the product of Group III requires a second zone which is not required by the process of Group II. The product of Group III requires a second zone which is not required by the product of Group I whereas the product of Group I requires

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hydrocolloids in an elastomeric matrix and grottos which are not required by the product of Group III.

3. During a telephone conversation with Susan Bailey on 4/8/2010 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-13. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Objections

6. Claims 1 and 13 are objected to because of the following informalities:

7. Claim 1 is indefinite in that both the diameter and average size are the same properties. The average size is known as the average diameter as seen in the specification of the present invention. In order to avoid confusion, the Examiner

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interprets the limitations as both the diameter and the average diameter. Appropriate correction is required.

8. Claim 13 recites the limitation "adhesive element" in line 2. There is insufficient antecedent basis for this limitation in the claim. The "adhesive element" should be "absorbing element". Appropriate correction is required.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-3, 5-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilman et al (EP 0 806 210).

Regarding claim 1, Gilman et al (EP 0 806 210) discloses an absorbing element comprising an elastomeric matrix with hydrocolloids having adhesive properties (Fig. 1 #14 "adhesive layer"; col. 3, line 50-col. 4, line 5) wherein the first facade of the absorbing element comprises grottos of at least 5 μm in diameter (Fig. 7 #18' "depressions"; col. 4, lines 25-34; col. 6, line 48-col. 7, line 5).

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Gilman et al (EP 0 806 210) does not appear to disclose the absorbing element comprising the average diameter of the grottos being less than 300 μm .

However, it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the average diameter of the grottos to be less than 300 μm in order to have prevent the skin from making adhesive contact with the barrier material and to prevent the depressions from being closed or obliterated from deformation of the adhesive material (col. 5, lines 48-55) for the intended application, and this is supported by MPEP 2144.05(II)(A).

“[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%).

Regarding claims 2 and 3, the grottos being obtained by heat treatment or heating of the absorbing element is a process limitation in a product claim.

“Even though the product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” (*In re*

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Thorpe, 227 USPQ 964,966) Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product (In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983), MPEP 2113).

Regarding claim 5, Gilman et al (EP 0 806 210) discloses the absorbing element comprising the first façade being adapted for releasable adhesion (col. 3, line 50-col. 4, line 5).

The first façade being adapted for releasable adhesion is also an intended use limitation.

The limitation(s) “adapted for releasable adhesion” is (an) intended use limitation(s) and is not further limiting in so far as the structure of the product is concerned. Note that “in apparatus, article, and composition claims, intended use must result in a **structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. **If the prior art structure is capable of performing the intended use, then it meets the claim.** In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art.” [emphasis added] *In re Casey*, 370 F.2d 576,

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152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). See MPEP § 2111.02.

Regarding claim 6, Gilman et al (EP 0 806 210) discloses the absorbing element comprising the hydrocolloid being pectin, gelatin, sodium or calcium carboxymethylcellulose, or karaya (col. 3, line 50-col. 4, line 5).

Regarding claim 7, Gilman et al (EP 0 806 210) discloses the absorbing element comprising tacky elastomeric matrix (it is well established that the elastomeric matrix is self-adhesive) (col. 3, line 50-col. 4, line 5).

Regarding claim 8, Gilman et al (EP 0 806 210) discloses the absorbing element comprising the elastomeric matrix being a rubbery elastomeric base (col. 3, line 50-col. 4, line 5). The elastomeric matrix is rubbery in that it is deformable.

Regarding claim 9, Gilman et al (EP 0 806 210) discloses the absorbing element comprising the elastomeric matrix not flowing at room temperature (col. 3, line 50-col. 4, line 5).

Regarding claim 10, the grottos being obtained by heat treatment of the first façade of the absorbing element with electromagnetic radiation with a wavelength of more than 400 nm is a process limitation in a product claim.

Regarding claim 11, the grottoes being obtained by heat treatment comprising irradiation of the first faced with an infrared laser is a process limitation in a product claim.

Regarding claim 12, Gilman et al (EP 0 806 210) does not appear to disclose the absorbing element comprising the average diameter of the grottoes being less than 200 μm .

However, it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the average diameter of the grottoes to be less than 200 μm in order to have prevent the skin from making adhesive contact with the barrier material and to prevent the depressions from being closed or obliterated from deformation of the adhesive material (col. 5, lines 48-55) for the intended application, and this is supported by MPEP 2144.05(II)(A).

“[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.).

Regarding claim 13, Gilman et al (EP 0 806 210) discloses the absorbing element being part of a medical device such as an ostomy device (col. 2, lines 41-45).

11. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilman et al (EP 0 806 210) in view of Lipman (US 6,326,421).

Gilman et al (EP 0 806 210) is relied upon as described above.

Gilman et al (EP 0 806 210) does not appear to explicitly disclose the absorbing element being a pressure-sensitive adhesive.

However, Lipman (US 6,326,421) discloses the absorbing element being a pressure-sensitive adhesive (col. 1, lines 16-22).

Gilman et al (EP 0 806 210) and Lipman (US 6,326,421) are analogous art because they are from the same field of absorbing elements.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Gilman et al (EP 0 806 210) and Lipman (US 6,326,421) before him or her, to modify the absorbing element of Gilman et al (EP 0 806 210) to include the pressure-sensitive adhesiveness of Lipman (US 6,326,421) in that having a pressure sensitive adhesive with hydrocolloids provides dual attributes of being inherently absorbent and inherently adhesive (col. 1, lines 16-22).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SATHAVARAM I. REDDY whose telephone number is (571) 270-7061. The examiner can normally be reached on 8:00 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Ruthkosky can be reached on (571) 272-1291. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SATHAVARAM I REDDY/
Examiner Art Unit 1785

/Betelhem Shewareged/
Primary Examiner, Art Unit 1785